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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/737,346

12/16/2003

David L. Patton

86559F-P

6021

7590  
Pamela R. Crocker  
Patent Legal Staff  
Eastman Kodak Company  
343 State Street  
Rochester, NY 14650-2201

08/03/2007

EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

08/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/737,346

Applicant(s)

PATTON ET AL.

Examiner

Sharon E. Kennedy

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 43-55, 58, 77-84 and 87-90 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-42 is/are allowed.
- 6) ☒ Claim(s) 1, 11, 14-17, 20, 21, 56, 66, 69-72, 75, 76, 85, 86 is/are rejected.
- 7) ☒ Claim(s) 2, 12, 13, 18, 19, 57, 59-65, 67, 68, 73 and 74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 07/14/2005; 12/16/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Double Patenting*

Note is made of the double patenting rejection set forth in applicant's related 10/868,730, having a filing date that is later than this application, and the terminal disclaimer filed therein. There is no need to make a rejection under double patenting in this application in view of the other since the applications are already co-owned and there would be no term shortening.

### *Election/Restrictions*

Applicant's election without traverse of Group I in the reply filed on May 25, 2007 is acknowledged.

Claims 22, 57 are allowable. The restriction requirement between the species set forth in the Office action mailed on May 25, 2007, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 24-27 and 59, directed to the specific antimicrobial material and/or the diffusion layer, are no longer withdrawn from consideration because the claims require all the limitations of an allowable claim. However, claims 3-10, 43-55, 58, 77-84, 87-90 remain withdrawn from consideration because they do not require all the limitations of an allowable claim, or are directed to a non-elected group.

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In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Claim Objections***

Claim 61 is objected to because of the following informalities: It does not end in a ".". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 21, 85, 86 are rejected under 35 U.S.C. 102(e) as being anticipated by Malik, US 6,897,348. Regarding claim 1, Malik discloses an adhesive bandage comprising antimicrobial layer 90. The claimed flexible support layer is anticipated by Malik absorbent pad 80. The flexible adhesive layer is anticipated by Malik adhesive 77. Note that the perforated barrier layer 85 may be absent (column 8, line 14), which would meet the claim limitation that the layers be "adjacent." Regarding claim 11, applicant's claimed support layer may be cellulose. Malik discloses the use of cellulose in column 7, line 52.

Claims 1, 14, 21, 56, 66, 69, 76, 85, 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al., US 5,232,702. While the Pfister et al disclosure is primarily directed to providing a pressure sensitive adhesive, the disclosure anticipates the claims. Regarding claim 1, Pfister shows rate controlling member 36 which anticipates applicant's claimed support layer. See especially figure 3. Liquid reservoir layer 34 anticipates applicant's claimed antimicrobial layer. Adhesive layer 38 anticipates applicant's claimed flexible adhesive layer. Regarding claim 14, see column 8, lines 10-11.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-17, 20, 70, 71, 72, 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al. '702. Regarding claims directed to the subbing layer, the examiner takes the position that in view the Pfister bandage is cohesive and does not fall apart, there is a layer, or it would be obvious to apply a layer of material between, particularly an adhesive layer, to join the layers together. Regarding the claimed thicknesses, it would be obvious to one of ordinary skill in the art to modify the Pfister bandage so it have various thicknesses as desired per particular application. What is important in the dimensions is that the devices are thin layers of material which are designed to be highly flexible.

#### ***Allowable Subject Matter***

Claims 22-42 are allowed.

Claims 2, 12, 13, 18, 19, 57, 59-65, 67, 68, 73, 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: None of the prior art discloses or suggests the flexible multilayered medium comprising the adhesive layer, the antimicrobial layer in combination with the visual indicator indicating the effectiveness of the antimicrobial. In addition, none of the prior art discloses or suggests the medium wherein the adhesive layer is either a repositionable adhesive or a flexible static cling vinyl. Claims directed to the diffusion layer are also allowable in view that the transdermal bandages and other prior art does not disclose an additional diffusion layer. Applicant's support layer is between the adhesive and support layer. Transdermal bandages also commonly contain layers between the adhesive and the drug reservoir, but they are rate controlling membranes. Applicant claims a diffusion layer in addition to the support layer. Transdermal bandages do not have several layers between the adhesive and the drug in view that one suffices. Of course, applicant's invention is not a transdermal bandage, but the layers are similar in that there is a drug contained therein, so this art must be considered as relevant.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ansell, US 5,183,664, and Hori et al., US 5,814,032, disclose a thin film adhesive dressing having a support member, an adhesive layer and an

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antimicrobial, however, the adhesive layer and the antimicrobial are not separate layers as claimed by applicant.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Sharon E. Kennedy/*

Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615